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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/743,364	12/22/2003		Harry S. Sowden	MCP0293-DIV2	7973	
27777	7590	08/10/2006		EXAMINER		
PHILIP S.		= '	DAVIS, ROBERT B			
JOHNSON (ONE JOHN)		ON OHNSON PLAZA	ART UNIT	PAPER NUMBER		
NEW BRUN	NSWICK,	NJ 08933-7003	1722			
				DATE MAILED: 08/10/2000	DATE MAILED: 08/10/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
·		10/743,364	SOWDEN ET AL.				
	Office Action Summary	Examiner	Art Unit				
	•	Robert B. Davis	1722				
	The MAILING DATE of this communication app						
Period for Reply							
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing end patent term adjustment. See.37 CFR 1.704(b).	ATE OF THIS COMMUNI 36(a). In no event, however, may a rill apply and will expire SIX (6) MON cause the application to become Al	CATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status	•						
1)🛛	Responsive to communication(s) filed on 23 Ju	ne 2006.					
2a)⊠	This action is FINAL . 2b) ☐ This action is non-final.						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
5)□ 6)⊠ 7)□	Claim(s) 13-15,17-20 and 40-47 is/are pending 4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) 13-15,17-20 and 40-47 is/are rejected Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.	·				
Application Papers							
	The specification is objected to by the Examiner	•					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
, —	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
Attachmen	t(s)						
_	e of References Cited (PTO-892)		Summary (PTO-413)				
3) 🛛 Inform	e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>5/19/06</u> .		s)/Mail Date Informal Patent Application (PTO-152) 				

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Art Unit: 1722

Response to Amendment

Specification

1. The disclosure is objected to because of the following informalities:

Page 11, line 6 to page 12, line 6, contains text that is outlined by a rectangle and shaded. This portion of the text should be resubmitted without the outlining and shading. Clean replacement sheets are required.

Page 21, line 27, after "serial no." there is a blank space which must be filled in to reflect the serial number of the related application which has the docket number MCP 274.

Page 58, lines 20 and 29-31, contains text that is outlined and shaded. A clean replacement sheet is required.

Page 62, lines 26-27, contains text that is outlined and shaded. A clean replacement sheet is required.

Page 63, lines 15-26, contains text that is outlined and shaded. A clean replacement sheet is required.

These matters must be corrected before the application can be passed to issue.

A copy of pages 11, 12, 21, 58, 62 and 63 is attached as appendix A to this office action to illustrate the above mentioned problems.

Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 13-15, 17-20 and 40-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 of copending Application No. 10/734,337. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims have substantial overlapping subject matter. Claim 13 of the instant application is fully encompassed by claim 16 of 10/734,337. The instant "powder recovery system for removing excess powder from the vicinity of the die cavity" is encompassed by the phrase "means for recovering powder trapped by said filter." Claim 16 of –337 recites "a recycling means for recovering powder trapped by said filter and means for recycling said recovered powder back to said die cavity" Claim 40 of the instant application is fully encompassed by claim 15 of 10/734,337 as the instant "a purge system for removing powder from said filter" is a more general way of stating "a source of pressurized gas, a

conduit for placing said pressurized fluid in flow communication with said filter so as to purge said trapped powder from said filter."

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claims 13, 15, 17, 40 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al (Soviet reference 662370 A: figures 1-3 and the English abstract) taken together with Bullock (5,667,158: figures 1 and 2; column 1, lines 16-30; and column 3, lines 31-47).

Belousov et al disclose an apparatus for compression molding of dosage forms (tablets), the apparatus comprising: a suction source (vacuum from the abstract attached to hose (16), a die cavity (4) having a first port (bottom opening of the die) for placing the die cavity in flow communication with the suction source (during the filling period-abstract), a second port (top opening of the die) for placing the die cavity in flow communication with a supply of powder, such that the suction source assists powder in flowing into the cavity; a filter (19) disposed between the suction source and the second port. The reference fails to disclose a powder recovery system to purge.

Bullock et al disclose a reclaim system for use with a pharmaceutical tablet compression machine, comprising: a filter (114) for collecting material dust, a compressed air source (128) to purge dust from the filter and a canister (112) which feeds dust back to a raw material source (C). The reference fulfills a long felt need for reusing raw material collected from the compression molding machine to save material costs. The feeding of the collected particulate back to the raw material source is an indirect method of feeding the reclaimed powder back to the die cavity of the compression molding press.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Belousov et al by adding a mechanism for recycling collected raw material as disclosed by Bullock et al for the purpose of saving on material costs by collecting discarded material from a compression molding machine.

7. Claims 14, 20, 41 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al taken together with Bullock et al as applied to claims

13, 15, 17, 40 and 42-44 above, and further in view of Campbell (3,430,532: figures 2-6 and column 2, lines 3-28).

The combination of Belousov et al and Bullock et al disclose all claimed features except for the second port being located in a wall of the die wherein the opening is closed upon upward movement of a bottom plunger or the use of a feed shoe which covers a plurality of dies on a die table as it is rotated past the feed shoe.

Campbell discloses a compression molding machine having a die (18) having openings (98) connected to a vacuum source for assisting in the quick, uniform loading of the die and a feed head (84) covering a plurality of dies (18) on a die table (86). It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Belousov et al by using a lateral opening of the die connected to a vacuum source for assisting in filling of the die as disclosed by Campbell for the purpose of assuring uniform filling of the plurality of dies. It would have been further obvious to modify the apparatus of Belousov et al by using a feed head that covers a plurality of dies on a die table as disclosed by Campbell for the purpose of feeding particulate material to a plurality of dies.

Response to Arguments

8. Applicant's arguments filed June 23, 2006 have been fully considered but they are not persuasive. Applicant argues that claims 13 and 40 have been amended to provide that the apparatus includes a powder recovery system that can remove excess powder from the vicinity of the die cavities and recycle recovered powder from the filters back into the die cavities and that the claims of the '337 application do not include these

features. The examiner submits that claim 16 of the '337 application substantially include these features as discussed in paragraph 3 of this office action.

Applicant further argues that the combination of Belousov et al and Bullock do not disclose or suggest recycling means for recovering powder trapped by the filter and recycling the recovered powder back into the die cavity. The instant application clearly has two species of recycling the recovered powder from the filter to the die cavity. These will be called the direct and indirect recycling devices. The indirect device is clearly shown in figure 25. The direct device is clearly shown in figure 24. The examiner respectfully submits that the device disclosed by Bullock is an indirect method of recycling the recovered powder to the die cavity as the recovered powder is directed back to the material source. It is clear that intention of the material source is to feed powder to the die cavities of the compression-molding machine. Hence, the combination of Belousov et al and Bullock disclose an indirect recycling device for use with a compression-molding machine. Applicant broadly claims the recycling device. The claim phraseology is not being considered as a means-plus-function limitation.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 571-272-1129. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B. Davis Primary Examiner Art Unit 1722

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MCP 293

compression rollers.

Appendix A

The invention also provides a dosage form comprising a medicant, said dosage form prepared by molding a flowable material, said dosage form having no more than one axis symmetry and being substantially free visible defects.

5 **Brief Description of the Drawings** Figures 1A and 1B are examples of dosage forms made according to the invention. Figure 2 is a flow chart of an embodiment of the method of the invention. Figure 3 is a plan view, partially schematic, of a system for manufacturing dosage forms according to the invention 10 Figure 4 is an elevational view of the system shown in Figure 3 Figure 5 is a three dimensional view of a compression module and transfer device according to the invention Figure 6 is top view of a portion of the compression module shown in Figure, 5 15 Figure 7 depicts the path of one row of punches of a compression module during a revolution of the compression module Figure 8 depicts the path of another row of punches of the compression module during a revolution of the compression module Figure 9 is a partial cross-section of a compression module during 20 compression. Figure 10 is a gnoss section taken through line 10 10 of Figure 9. Figure 11 is a cross-section taken through line 11-11 of Figure 10 Figure 12 is an enlarged view of the die cavity area circled in Figure 11 1. . . . 25 Figure 12A shows another embodiment of a die cavity of the compression module Figure 13 is a top view of the fill zone of the compression module. Figure 14 is a cross-sectional view of a portion of the fill zone of the compression module. .30 Figure 15 is a cross section taken through line 15-15 of Figure 6. Figure 16 is a view taken along an arc of the compression module during compression. Figures 17A-C illustrate one embodiment of a "C" frame for the

Figures 18A-C illustrate another embodiment of a "C" frame for the compression rollers. Figures 19A-C illustrate a preferred embodiment of a "C" frame for the compression rollers. Figure 20 is a top view of the purge zone and the fill zone of the 5 compression module. Figure 21 is a cross-section taken through line 21-21 of Figure 20. Figure 22 is a cross-section taken through line 22-22 of Figure 20. Figure 23 illustrates an embodiment of a powder recovery system for the 10 compression module. Figure 24 is a cross-section taken along line 24-24 of Figure 23. Figure 25 shows an alternative embodiment of a powder recovery system for the compression module. Figures 26A-C illustrate one embodiment of a thermal cycle molding 15 module according to the invention in which dosage forms per se are made. Figures 27A-C illustrate another embodiment of a thermal cycle molding module in which a coating is applied to a substrate. Figures 28A-C illustrate a preferred embodiment of a thermal cycle molding module in which a coating is applied to a substrate. 20 Figure 29 is a three dimensional view of a thermal cycle molding module according to the invention. Figure 30 depicts a series of center mold assemblies in a thermal cycle molding module. Figure 31 is a cross-section taken along line 31-31 of Figure 30. 25 Figures 32-35 depict the opening, rotation and closing of the center mold assembly with the lower retainer and upper mold assembly. Figures 36 and 37 are cross-sectional views of a lower retainer of a thermal cycle molding module. Figure 38 and 39 are top views of an elastomeric collet of a lower retainer. 30 Figure 40 shows a preferred cam system for the center mold assembly of the thermal molding module.

embodiment of a valve actuator assembly therefor.

Figure 41 is a cross-section of the center mold assembly showing one

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weight of compressed dosage forms made according to the invention is typically less than about 2%, preferably less than about 1%.

In addition, better content uniformity can also be achieved with the present vacuum fill system, since little mechanical agitation is required to cause the powder to flow into the die cavity. In conventional tablet presses, the mechanical agitation required to assure die filling has the adverse effect of segregating small from large particles.

Known powder filling equipment employ vacuum to fill uncompressed powders into capsules or other containers. See. For example, Aronson, U.S. Patent No. 3,656,518 assigned to Perry Industries, Inc. However, these systems have filters that are always in contact with the powder and therefore unsuitable for adaptation to compression machines. Forces on the order of 100kN can be experienced during compression of powders into dosage forms. Such high forces would damage the filters. US Patent No. 4,292,017 and US Patent No. 4,392,493 to Doepel describe a high speed rotary tablet compression machine which uses vacuum die filling. However separate turntables are used for filling and compression. Dies are filled on the first turntable and thereafter transferred to a separate turntable for compression. Advantageously, according to the invention, the filters are protected during compression, since the lower punches move above the filter port prior to the die cavities entering the compression zone.

Powder is fed into the die cavities 132 in the fill zone 102. The powder may preferably consist of a medicant optionally containing various excipients, such as binders, disintegrants, lubricants, fillers and the like, as is conventional, or other particulate material of a medicinal or non-medicinal nature, such as inactive placebo blends for tableting, confectionery blends, and the like. One particularly preferred formulation comprises medicant, powdered wax (such as shellac wax, microcrystalline wax, polyethylene glycol, and the like), and optionally disintegrants and lubricants and is described in more detail in commonly assigned co-pending United States Patent Application Serial No._______, entitled "Immediate Release Tablet" (attorney docket number MCP 274) which is hereby incorporated by reference.

Suitable medicants include for example pharmaceuticals, minerals, vitamins and other nutraceuticals. Suitable pharmaceuticals include analgesics, decongestants, expectorants, antitussives, antihistamines, gastrointestinal agents, diuretics, bronche dilators, sleep-inducing agents and mixtures thereof. Preferred pharmaceuticals include acetaminophen, ibuprofen, flurbiprofen, ketoprofen, naproxen, diclofenac, aspirin, pseudocola drine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan,

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The thermal setting molding module 400 is a rotary apparatus comprising multiple hot injection nozzles and cold molding chambers. Each molding chamber has its own nozzle. Advantageously, the volume of the molding chambers is adjustable.

In a preferred embodiment of the invention, the thermal setting molding module is used to make inserts for dosage forms. The inserts can be made in any shape or size. For instance, irregularly shaped inserts (or dosage forms per se) can be made, that is shapes having no more than one axis of symmetry. Generally however, cylindrically shaped inserts are desired.

The inserts are formed by injecting a starting material in flowable form into the molding chamber. The starting material preferably comprises an medicant and a thermal setting material at a temperature above the melting point of the thermal setting material but below the decomposition temperature of the medicant. The starting material is cooled and solidifies in the molding chamber into a shaped pellet (i.e., having the shape of the mold). Injection and molding of the inserts preferably occurs as the thermal setting molding module 400 rotates. In a particularly preferred embodiment of the invention, a transfer device 700 (as described above) transfers shaped pellets from the thermal setting molding module to a compression module 100 (also described above) as generally shown in Figure 2, to embed the shaped pellets into a volume of powder before such powder is compressed into a dosage form in the compression module.

The starting material must be inflowable form. For example, it may comprise solid particles suspended in a molten matrix, for example a polymer matrix. The starting material may be completely molten or in the form of a paste. The starting material may comprise a medicant dissolved in a molten material. Alternatively, the starting material may be made by dissolving a solid in a solvent, which solvent is then evaporated from the starting material after it has been molded.

The starting material may comprise any edible material which is desirable to incorporate into a shaped form, including medicants, nutritionals, vitamins, minerals, flavors, sweeteners, and the like. Preferably, the starting material comprises a medicant and a thermal setting material. The thermal setting material may be any edible material that is flowable at a temperature between about 37 and about 120°C, and that is a solid at a temperature between about 3 and about 35°C. Preferred thermal setting materials include water-soluble polymers such as polyalkylene glycols, polyethylene oxides and derivatives, and sucrose esters; fats such as cocoa butter, hydrogenated vegetable cil such as palm

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Preferably, the pistons 434 are adjustably controlled by the position of cam follower 470 and associated cam track 468. Pistons 434 are attached to piston attachment block 436 by suitable mechanical means so that pistons 434 move with piston attachment block 436. Piston attachment block 436 slides along the shafts 464 up and down.

Preferably, there are two shafts 464 as shown in Figure 86. Mounted to piston attachment block 436 is cam follower 470. One or more springs 466 bias piston attachment block 436 and therefore pistons 434 into the inject position as viewed in Figure 85C. As thermal setting mold assembly 420 travels with rotor 402, cam follower 468 riding in its cam track actuates pistons 434 into the eject position, which empties the molding chamber in preparation for the next cycle (Figure 85D).

Accordingly, during operation of the thermal setting molding module 400, nozzles 410 move up during rotation of the thermal setting molding module 400 and inject a starting material into molding chambers 422. Next, starting material is hardened within the molding chambers 422 into shaped pellets. Nozzles 410 are then retracted from the molding chambers. All of this occurs as the molding chambers 422 and nozzles 410 are rotating. After the starting material has hardened into shaped pellets, it is ejected from the molding chambers. See Figures 87 and 88.

When used with a transfer device 700 according to the invention, the transfer device 700 rotates between the molding chambers 422 and plate 428. The retainers 330 of the transfer device 700 receive the shaped pellets and transfers them to the another operating module, for example a compression module 100. In the case of coupling a thermal setting molding module 400 with a compression module 100 via a transfer device 700, transfer device 700 inserts a shaped pellet into each die cavity 132 after the fill zone 102 but before the compression zone 106 of the compression module. It will be appreciated that a linked thermal setting molding module 400, transfer device 700 and compression module 100 are synchronized so that a snaped pellets placed into each die cavity 132. The process is a continuous one of forming shaped pellets, transferring the shaped pellets, and inserting the shaped pellets.

The thermal setting molding module has several unique reatures. One is the ability to mass produce shaped pellets relatively rapioly, in particular molded dosage forms comprising polymers that are typically solids or solid-like between about 0 and about 3.79°C. The thermal setting moiding module accomplishes this is by heating the

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starting material prior to injecting it into the molding chambers and then cooling the starting material after injection.

Another unique feature of the thermal setting molding module is the adjustable volume of the molding chambers. Adjustability and tuning of volume and therefore weight is especially advantageous for the production of shaped pellets comprising high potency or highly concentrated drugs, which are dosed in small amounts. Another advantage of the thermal setting molding module is that it can employ liquids. Unlike a particulate solid, such as powders typically used to make dosage forms, the volume of a liquid is relatively invariable at constant temperature. Density variations, which are troublesome in powder compression, are therefore avoided with liquids. Very accurate weights, especially at very low weights (i.e. with starting materials comprising high potency medicants) are achievable. Moreover, blend uniformity is also less assured with solid powders. Powder beds tend to segregate based on differences in particle size, shape, and density.

Another advantage of the thermal setting molding module is that it molds starting material while continuously rotating while continuously devices resulting in a continuous process. Conventional nolding operations are typically stationary and have one hozzle feeding multiple mold avittes a Runners are often formed using in conventional equipment. By providing a sozzle for each molding chamber, numers are climinated. Preferably one control valve introls multiple hozzles. This simplifies the design of the thermal setting molding module reducing costs. The thermal setting molding module may, of course be designed to negate without rotation of the rotor, for example on an indexing basis whereby a ationary group of nozzles engages molding chambers on a indexing rotary turn table or a leaf of localizing indexing belt of platents ystem. However, by using a rotary system but rates can be achieved since products are continuously produced.

Examples. This invention is not confined to the specific limitations set forthing in the specific limitation set for the specific limitation set

In the examples, measurements were made as follows.